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RICHARD J. BERMAN
ARENT FOX KINTNER PLOTKIN & KAHN, PLLC
1050 CONNECTICUT AVENUE
SUITE 600
WASHINGTON, DC 20036-5339

EXAMINER	
PORTNER, VIRGINIA ALLEN	
ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 11/07/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/284,233	Meyer
Examiner	**Art Unit**
Portner	1645

-- The MAILING DATE f this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Aug 19, 2002*.

2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1, 3, 5-11, and 13-23* is/are pending in the application.

4a) Of the above, claim(s) *16* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1, 3, 5-11, 13-15, and 17-23* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims *1, 3, 5-11, and 13-23* are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Claim 23 has been submitted. Claims 1, 3,5-11, 13-23 are pending Claims 2, 4 and 12 have been canceled. Claim 16 remains withdrawn from consideration. Claims 1, 3, 5-11, 13-15 and 17-23 are under consideration.

Interview Summary

1. Applicant's summary of the informal interview held on July 8, 2002, that the examiner's position on Dr. Meyer's declaration sets for data that is not commensurate in scope with the claimed invention is correct. Additional responses to Applicant's supplemental arguments are set forth below.

Objection/Rejections Withdrawn

2. Claim 2 rejected under 35 U.S.C. 112, second paragraph, for broadening the scope of claim 1, in light of claim 2 having been canceled.
3. Claims 2-4, 8-11, 13-15, 17-21 rejected under 35 U.S.C. 112, second paragraph for reciting the phrase "the pathogen", "the attenuated pathogen" or "said pathogen", and depend from claim 1, in light of the amendment of the claims to recite the term "cell"
4. Claim 6 rejected under 35 U.S.C. 112, second paragraph for reciting the phase "Helicobacter antigen" and depends from claim 1, in light of the amendment of claim 6 to recite "Helicobacter immunogen".
5. Claims 1,2,5 and 10 rejected under 35 U.S.C. 102(b) as being anticipated by Evans et al (1993), in light of claim 1 having been amended to recite an attenuated Salmonella and claim 2 which broadened the scope of claim 1 has been canceled.
6. Claims 1-2, 5-6,7-10 rejected under 35 U.S.C. 102(b) as being anticipated by Odenbreit et al (April 1996),in light of claim 1 having been amended to recite an attenuated Salmonella and claim 2 which broadened the scope of claim 1 has been canceled.
7. Claims 1,2,4,5, 10, 17 rejected under 35 U.S.C. 102(b) as being anticipated by Dore'-Davin et al (May 1996),in light of claim 1 having been amended to recite an attenuated Salmonella and claim 2 which broadened the scope of claim 1 has been canceled.

Rejections Maintained

8. Claims 1, 3, 5-11, 13-15, 17-22 and new claim 23 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the production of recombinant DNA, vectors, host cells, chimeric proteins and antigenic compositions that comprise Helicobacter antigens the instant specification, does not reasonably provide enablement for

preventive or therapeutic live vaccines that express any Helicobacter antigen, and compositions which comprise any nucleic acid sequence from Helicobacter as the active agent which is a mimeotope or immunogen that is encoded by a nucleic acid sequence that does not evidence original descriptive support. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims, for reasons of record in paper number 10, paragraphs 13 and 14.

8. Claims 1, 6-10, 13, 19-22 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, as no response was made with respect to the rejections set forth in paper number 22. The rejections are maintained for reasons of record in paper number 22, paragraph 30.

9. Claims 1, 5, 10, 11,13, 17-21 rejected under 35 U.S.C. 102(b) as being anticipated by Doidge (WO95/33482) in light of McKee (1992) for reasons of record in paper number 10, paragraph 18.

10. Claims 1, 5,10-11, 13-15, 17-22 and new claim 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Michetti (WO95/22987) for reasons of record in paper number 10, paragraph 20.

11. Claims 1, 3,5, 7-11,13-15, 17-22 and new claim 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Michetti (WO95/22987) in view of Russell et al (US Pat. 6,030,624) for reasons of record in paper number 10, paragraph 22.

12. Claims 1, 3,7-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Russell et al (US Pat. 6,030,624) in view of Bukanov et al (1994) for reasons of record in paper number 10, paragraph 23.

13. Claims 1, 5, 7-8, 10-11, 17-18 and new claim 23 are rejected under 35 U.S.C. 102(e) as being anticipated by Michetti et al (US Pat. 6,290,962, filing date Feb. 1994)for reasons of record in paper number 22, paragraph 32.

14. Claims 1, 13-15, 19-22 are rejected under 35 U.S.C. 102(e) as being anticipated by Michetti et al (US Pat. 6,290,962, filing date Feb. 1994), for reasons of record in paper number 22, paragraph 33.

Supplemental Response to Amendment

15. Applicant's Representative asserts that the Declaration submitted by Dr. Thomas F. Meyer under 37 CFR 1.132 filed August 22, 2001 is sufficient evidence to over come the rejections of claims 1-11, 13-15, 17, 19-21 and new claim 22. The traversal being directed

toward "a number of rejections" over the claims and asserts the Declaration provides evidence to obviate a number of rejections, and states the "positions advanced in the Declaration are valid based only upon the results obtained from using the P-t7 promoter (see Exhibit B of the Declaration)."

16. The examiner upon reconsideration of the Declaration dated August 22, 2001, could not find an Exhibit labeled "Exhibit B".

The Declaration was received by the examiner with 3 pages of narrative and Exhibit 1 (page 4) and Exhibit 2 (page 5). Exhibit 1 shows three constructs that have the P-t7 promoter, specifically CREA1396 which expresses HylB; CREA1398 which expresses a citrate synthase homolog; and SL3261::YZ222, Δthy[pT7-97], which expresses the urease A subunit associated with the P-t7 promoter and Urease B subunit associated with an internal promoter.

The nucleic acid coding sequences for the HylB and the citrate synthase homolog lack original descriptive support in the instant specification and the coding sequences contained in the constructs were not publicly known, thus CREA1396 and CREA1398 do not provide evidence commensurate in scope with the instantly claimed invention. Only coding sequences for AlpA, AlpB, UreA and UreB are disclosed in the instant specification defined by SEQ ID Nos 1-7.

With respect to SL3261::YZ222, Δthy[pT7-97], the examiner was unable to find original descriptive support for a YZ222 construct, a Δthy strain. No Δthy strains are described in the instant specification. Also with respect to the SL3261::YZ222 construct, the examiner was unable to find original descriptive support for the combination of urease A subunit P-t7 promoter

together with a urease B subunit/internal promoter. What the "internal promoter" sequence is, is also not described in the Declaration, nor in the specification.

Therefore, despite the fact that these constructs utilized a promoter that was described in the instant specification, the nucleic acid sequence for HylB, the citrate synthase homolog, and the complementary coding sequence inserted in the plasmid for the deletion mutant Δthy strain have not been described in the instant specification. The data presented in the Declaration is not commensurate in scope with the instantly claimed invention. All of the instantly claimed recombinant attenuated Salmonella cell compositions are not limited to any specific combination of Helicobacter pylori nucleic acid molecules nor any specific promoters.

Exhibit 2 shows data presented with respect to various antigens and carriers, and shows not data with respect to any specific promoters as asserted by Applicant.

17. The scope of enablement rejection is traversed on the grounds that the P-t7 promoter constructs used to generate data of the Declaration of August 22, 2002 "demonstrate the enablement and efficacy of the claimed invention."

18. It is the position of the examiner that the utilization of nirB, phoP or the internal promoter which do not evidence original descriptive support in the instant specification presents evidence that is not commensurate in scope with the instantly claimed invention.

In addition to the promoters differing from those described in the instant specification, the claims of which are not limited to any specific promoter, any specific sequence, any specific

peptide mimotope, any specific recA mutant (instant claim 9), an specific eukaryotic promoter or any specific second nucleic acid molecule. The examiner could not find original descriptive support for the specific balanced lethality mutant of Salmonella used, the coding nucleic acid sequences for citrate synthase, and HylB and the various combinations of expression sequences and coding sequences presented in the Declaration. The data presented in the Declaration is not commensurate in scope with the instantly claimed invention. The scope of enablement rejection of claims 1-12, 13-15 and 17-21 under 35 U.S.C. 112, first paragraph and the prior art rejections under 35 U.S.C. 103 are maintained.

Response to Arguments

19. Applicant's arguments filed August 19, 2002 have been fully considered but they are not persuasive.

20. The rejection of claims 1, 5, 10, 11,13, 17-21 under 35 U.S.C. 102(b) as being anticipated by Doidge (WO95/33482) in light of McKee (1992) is argued by incorporating arguments presented December 20, 2000, and making the statement that the examiner response to Applicant's arguments was not responsive.

21. It is the position of the examiner that specific responses to Applicants arguments were set forth in paper number 22, dated March 11, 2002; those arguments are herein incorporated by reference.

22. Applicant asserted that the Doidge reference vaccine "acts protectively against H.felis" and fails to show protection against H.pylori.

23. It is the position of the examiner that the Doidge et al reference is directed to "treatment or prevention of Helicobacter infection in a mammalian host", specifically "H.pylori or H.felis" (see WO95/33482, front page, abstract; see page 11, lines 1-12; page 17, claims 23-25). All of the instantly claimed compositions are not limited H.pylori coding sequences as asserted. All of the claims incorporate any Helicobacter coding sequence into the mutant Salmonella strain. Applicant's arguments are not commensurate in scope with the instantly claimed invention.

24. The rejection of claims 1,5,10-11, 13-15, 17-22 and new claim 23 under 35 U.S.C. 102(b) as being anticipated by Michetti (WO95/22987) is traversed on the grounds that:

"an attenuated bacterium as a live carrier of urease or other immunogen is not discussed anywhere in the Michetti reference" and "it is submitted that no connection between a carrier for providing the adjuvant and a carrier for expressing the antigen is disclosed in Michetti."

25. Applicant's arguments filed with respect to Michetti have been fully considered but they are not persuasive because Michetti et al (WO95/22987) at page 23 discusses "suitable mucosal adjuvants" that include "genetically engineered attenuated live vectors such as viruses or bacteria (see page 23, lines 4-12). The live bacterial vectors or carrier system is further described to include Salmonella typhimurium, and Salmonella typhi. The bacterial vector or carrier system is

disclosed for mucosal administration and recombinant expression of urease (see Michetti et al, page 48, lines 15-25 and page 49, lines -12; see claims 25-26 and claims 61-62 and 65).

27. Applicant asserts that the composition of Michetti et al (WO95/22987) "does not disclose recombinant attenuated Salmonellae which are capable of protecting vaccinated animals", that the vaccine of Michetti will not work without an adjuvant, and does not teach that recombinant Salmonella could achieve protective immunity without an adjuvant".

28. It is the position of the examiner that the recombinant attenuated Salmonella cell that comprises an H.pylori urease nucleic acid sequence anticipates the instantly claimed invention. The recombinant attenuated Salmonella cell is disclosed to be a mucosal delivery system for the encoded Helicobacter urease antigen(s), a known protective antigen (see figures of Michetti et al). The attenuated Salmonella cell would serve to not only deliver the encoded Helicobacter immunogen, but would also serve to stimulate and enhance immune response analogous to that of an adjuvant. No structural distinctions have been claimed.

29. Michetti is further asserted to induce " humoral and cellular type II immune responses while most Salmonellae induce a type I humoral immune response" and concludes that " it cannot be concluded from the teachings of the Michetti patent that Salmonella could be used successfully for preparing a live vaccine."

29. It is the position of the examiner that the instantly claimed compositions are not required to induce a type II or type I immune response based upon the functional language recited in the claims. The arguments are not commensurate in scope with the instantly claimed invention.

With respect to teachings of the Michetti et al (WO95) patent that Salmonella could be used successfully for preparing a live vaccine, it is the position of the examiner, that based upon all comparable data, the composition of Michetti et al (WO95) and that of the instantly claimed invention are the same or equivalent compositions and would therefore evidence the equivalent functional characteristics.

In support of the examiner's position, Fulginiti et al (September 1995) is being cited who teaches the oral immunization of mice with a live attenuated S.typhimurium expressing H.pylori urease which is taught as a molecular approach to the control of infectious disease. In further support of this position, Krachenbuhl (July 8, 1996) is being cited who teaches a second generation vaccine aimed at enhancing the duration of protection which utilizes a live recombinant Salmonella typhimurium for expression of Helicobacter pylori urease antigen (see last few sentences of abstract).

Both Fulginiti et al and Krachenbuhl are references that teach recombinant Salmonella compositions that express H.pylori urease as a vaccine or means for controlling H.pylori infectious disease. Based upon these facts, inherently Michetti et al anticipates the now claimed invention. Atlas Powder Co. V IRECA, 51 USPQ2d 1943, (FED Cir. 1999) states "Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior

art...However, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer. "The Court further held that "this same reasoning holds true when it is not a property but an ingredient which is inherently contained in the prior art".

30. The rejection of claims 1, 3,5, 7-11,13-15, 17-22 and new claim 23 are under 35 U.S.C. 103(a) as being unpatentable over Michetti (WO95/22987) in view of Russell et al (US Pat. 6,030,624) is traversed on the grounds that "the Russell patent does not teach or suggest a protective live oral vaccine consisting of an attenuated Salmonella carrier that expresses Helicobacter immunogen.

31. It is the position of the examiner that the instantly claimed invention is not directed to a composition that is a "live oral vaccine *consisting* of an attenuated Salmonella carrier that expresses Helicobacter immunogen." All of the claims recite "comprising" language thus permitting the presence of other components. Applicant's arguments are not commensurate in scope with the claimed invention. Clearly Michetti in view of Russell teach, provide guidance and motivation for the construction of recombinant attenuated microbial pathogens, that comprise a recombinant AroA attenuated mutant Salmonella transformed to express a heterologous Helicobacter immunogen for the induction of a protective immune response directed against Helicobacter.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

33. Russell et al is traversed on the grounds that the reference "only provides information regarding humoral responses, and contains no disclosure as to whether a CT A2/B chimeric protein expressed in an attenuated bacterial carrier would induce such a high level of protective immunity after a single oral application."

34. It is the position of the examiner that Russell et al was cited to show an AroA or AroD mutant strain of Salmonella as a carrier for a heterologous H.pylori immunogen coding sequence, in association with a bacteriophage promoter. The combination of Michetti et al in view of Russell et al teaches the claimed composition and method that comprises the step of administering the recombinant live vector (see Michetti et al (WO95', page 31, paragraph 3, lines 11-19).

35. The rejection of claims 1, 3,7-11 under 35 U.S.C. 103(a) as being unpatentable over Russell et al (US Pat. 6,030,624) in view of Bukanov et al (1994) is traversed by asserting that the cited references " provide no suggestion or motivation regarding the Helicobacter immunogen or live vaccine of the present invention", that"Russell et al. does not teach or suggest an attenuated

pathogen comprising a Helicobacter immunogen that is capable of inducing protective immunity "; the instant invention is " capable of inducing protective immunity of about 100% after a single dose application" and "Bukanov et al fails to cure the deficiencies of Russell et al."

35. Applicant's arguments filed with respect to Russell in view of Bukanov have been fully considered but they are not persuasive.

The phrase "*immunological protection of the present invention*", is being read to mean immunological protection against Helicobacter infection. Clearly Russell suggests, teaches, and provides guidance for the construction of a recombinant attenuated microbial pathogens, that comprise a recombinant AroA attenuated mutant Salmonella transformed to express a heterologous Helicobacter immunogen for the induction of a protective immune response directed against Helicobacter, a pathogen known to be associated with gastric ulcers (col. 9, lines 46 and 66).

Russell et al suggest the formulation of vaccine compositions for Helicobacter. Vaccine antigens induce protective immunity. Bukanov was cited for what the reference taught with respect to known Helicobacter antigens and their use in the production of recombinant attenuated microbial pathogens. Bukanov taught the person of ordinary skill that urease nucleic acid sequences were known and could be incorporated into a attenuated microbial pathogen for expression. At the time of filing of the instant Application, urease was known to be a protective Helicobacter antigen. The person of ordinary skill in the art at the time the invention was made would have been motivated to use a known protective Helicobacter immunogen in the

formulation of a recombinant attenuated microbial pathogen for the induction of a protective immune response.

Arguments directed to the wherein statement recited in claim 21, " wherein the composition is administered as a single dose" does not exclude the administration of additional doses. Claim 21 defines the dose of claims 19 and 20 as a single dose, but the method may comprise the administration of multiple doses because the claims recite "comprising language" and the methods are not limited to only a single administration step. Applicant's arguments are not commensurate in scope with the claimed invention. The rejection of Russell in view of Bukanov is maintained for reasons of record.

36. The rejection of claims 1,5, 7-8, 10-11, 17-18 and new claim 23 under 35 U.S.C. 102(e) as being anticipated by Michetti et al (US Pat. 6,290,962, filing date Feb. 1994) was not traversed and therefore maintained for reasons of record in paper number 22, paragraph 32.

37. The rejection of claims 1, 13-15, 19-22 under 35 U.S.C. 102(e) as being anticipated by Michetti et al (US Pat. 6,290,962, filing date Feb. 1994), was not traversed and therefore maintained for reasons of record in paper number 22, paragraph 33.

Double Patenting

38. Amended Claims 1, 5 and 6 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1,5 and 6 of U.S. Patent No.

6,096,521 in view of Russell et al (US Pat. 6,030,624). Issued claims 1, 5 and 6 of U.S. Patent No. 6,096,521 are directed to "An isolated cell" "transformed with a vector" (recombinant) that comprises a DNA molecule which encodes AlpB, a secretory antigen adherence-associated lipoprotein B of H.pylori (definition of DNA of claim 1 SEQ ID No 1, of Haas et al, of U.S. Patent No. 6,096,521) , the cell being defined in the Hass et al specification to include within the scope of the claim any gram negative prokaryotic cell (see Hass et al, col. 6, lines 39-40). In view of Russell et al that teaches attenuated gram negative recombinant Salmonella cells for the expression of H.pylori immunogen (see Russell et al, col. 9, lines 34-36, line 66), the instantly claimed transformed recombinant cell of claims 1,5 and 6 would be an obvious species of the allowed claims 1, 5 and 6 which comprises the nucleic acid sequence of AlpB in a gram negative prokaryotic cells that comprises a vector for the expression of an H.pylori immunogen, the cell being one that is a prokaryotic cell known in the art for the expression of heterologous antigens, and was taught for the expression of H.pylori antigens. This rejection could be obviated through the filing of an effective terminal disclaimer.

Conclusion

39. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

40. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (703)308-7543. The examiner can normally be reached on Monday through Friday from 7:30 AM to 5:00 PM except for the first Friday of each two week period.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909. The fax phone number for this group is (703) 308-4242. The Group and/or Art Unit location of your application in the PTO will be Group Art Unit 1645. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to this Art Unit.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Vgp

October 29, 2002

LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600